

## **REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-24 are pending. Claims 3-5 and 7-23 have been withdrawn from consideration as directed to non-elected subject matter. Applicants reserve the right to file at least one continuation and/or at least one divisional application directed to any subject matter canceled herein.

Claims 1, 2, 6, and 24 have been amended herein. Basis for the amendment may be found in the specification and claims as-filed. Thus, no new matter is presented by way of the present Amendment.

### ***Objections to the Claims***

Claims 6 and 24 are objected to because they are purportedly drawn to non-elected subject matter. Applicant assumes the Office refers to the dependency of claims 6 and 24 in this regard. Claims 6 and 24 are amended to incorporate the subject matter of claim 3, upon which they depended. The objections are mooted.

### ***Rejections under 35 U.S.C. 101***

Claims 1 and 2 are rejected under 35 U.S.C. § 101 because the claimed invention is purportedly directed to non-statutory subject matter. Claims 1 and 2 are amended herein to recite isolated Par-4 proteins. The Par-4 proteins contemplated by the present invention do not exist in nature (Applicant notes that only the full length Par-4, of 1-322 amino acids, exists in nature). Thus, Applicant submits that this rejection is obviated.

### ***Rejections Under 35 U.S.C. § 112***

Claims 1, 2, 6 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. Claim 1 stands rejected for the recitation of "resistant to Par-4". With regard to "resistant", Applicant submits that Par-4 is the protein product of the gene *par-4*. The most important functional moiety is the protein, which

executes the action of the gene. Therefore, the cells are resistant to apoptosis by the Par-4 protein.

Claim 2 stands rejected for the recitation of specific Par-4 mutants. To this end, the recited mutants refer to rat prostate apoptosis response-4 (Par-4) amino acids (1-204, 137-221, respectively).

Claim 6 stands rejected for the recitation of "encoded by a nucleic acid contained in one or more sequences of claim 3". Claim 24 stands rejected for the recitation of "the amino acid sequence of claim 3". As noted above, claims 6 and 24 are amended herein to incorporate the subject matter of non-elected claim 3.

Claims 1, 2, 6 and 24 are rejected under 35 U.S.C. § 112, first paragraph as purportedly lacking enablement. The Office states that undue experimentation would be required to determine the amino acid substitutions and amino acids to be substituted within the presently claimed invention.

First, Applicant notes that the sequences contemplated by the present invention are those of the rat Par-4. Further Applicant submits that the Par-4 method of action and active domains of Par-4 are discussed in the present specification. For example, paragraph [0040] at page 14 cites to Sells et al., (*Cell Growth Differ.*, 1994, Vol. 5, pgs. 457-466) with regard to the Par-4 gene. Paragraph [0045] at pages 16-17 discloses Sells et al., (*Molecular and Cellular Biology*, 1997, Vol. 17, No. 7, pgs. 3823-2832) regarding active domains of Par-4. Pages 16-18 discuss information as to structure and function of Par-4. Par-4 mutants are disclosed on pages 21-22. Thus, Applicant submits the skilled artisan would be able to perform proper modifications without undue experimentation.

Applicant requests that the rejections under 35 U.S.C. § 112 be withdrawn.

### ***Claim Rejections Under 35 U.S.C. § 102***

Claims 1, 6 and 24 are rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Guo et al. (*Nature Medicine*, 1998, pages 957-62). Applicant submits that Guo et al. do not recite each and every element of the present invention.

As discussed in the present specification, the Par-4 of the present invention are able to cause selective induction of apoptosis in cancer cells. Guo discloses the deletion mutant Par-4 delta leu.zip, which lacks the leucine zipper domain, and Par-4

leu.zip, which contains only the leucine zipper domain. The mutants disclosed by Guo do not produce apoptosis. In fact, the leu.zip mutant disclosed in Guo actually inhibits apoptosis and thus are functioning in a different manner from the modified Par-4's of the present invention. The mutants of the present invention produce apoptosis in cancer cells, while Guo does not disclose any testing on human cancer cells.

Claim 6 is rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Darrow et al. (U.S. Patent Publication No. 2006/0141451). Applicant submits that Darrow et al. do not recite each and every element of the present invention. To this end, Par-4 in the context of the present invention stands for "prostate apoptosis response-4". In contrast, Darrow discloses protease activated receptor-4 as Par-4. These are two different genes. Thus, the proteins disclosed in Darrow are not those of the present invention.

Applicants request that the rejections under 35 U.S.C. § 102 be withdrawn.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Reply or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

Respectfully submitted,

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